

Application No. 10/031,353

Reply to Office Action

*REMARKS/ARGUMENTS**The Pending Claims*

Claims 1, 3-23, 57-65, and 67-91 are currently pending.

*The Amendments to the Claims*

Claim 1 has been amended to recite that the sample is subjected to electrophoresis in an aqueous solution. Claim 65 has been amended to replace the phrase "free solution" with "aqueous solution," and to recite that the sample is maintained in the sample channel as an aqueous free solution. These amendments are supported by the specification at, for example, page 22, lines 10-13, page 32, lines 6-10, page 33, lines 22-23, and page 38, lines 19-31. Claims 1, 18-21, 62-65, 81-83, and 89-91 also have been amended to clarify that *each* of the at least two or more molecules is imaged and distinguished, and to correct matters of form. Accordingly, no new matter has been added by way of these amendments.

*The Office Action*

The Office Action has made the following rejections:

- (a) claims 1, 3-8, 10-13, 15-22, 58, 60-65, 67-72, 74-76, 78-84, 86, and 88-91 are rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over U.S. Patent 6,485,625 ("the Simpson patent") in view of U.S. Patent 5,188,963 ("the Stapleton patent"),
- (b) claims 9 and 73 are rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over the combined disclosures of the Simpson patent and the Stapleton patent in further view of U.S. Patents 6,221,592 ("the Schwartz patent") and 5,215,883 ("the Chu patent"),
- (c) claims 14 and 77 are rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over the combined disclosures of the Simpson patent and the Stapleton patent in further view of U.S. Patents 6,586,193 ("the Yguerabide patent") and 6,120,667 ("the Hayashizaki patent"),
- (d) claims 23, 57, and 85 are rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over the combined disclosures of the Simpson patent and the Stapleton patent in further view of the Yguerabide patent and the Hayashizaki patent, and

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(e) claims 59 and 87 are rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over the combined disclosures of the Simpson patent and the Stapleton patent in further view of U.S. Patent 5,538,613 ("the Brumley patent").

The claims have been amended to place the application in condition for allowance or in better form for an appeal. Accordingly, reconsideration of the application is respectfully requested, and entry of the amendment is earnestly solicited.

*Discussion of Rejections Under 35 U.S.C. § 103*

Claims 1, 3-8, 10-13, 15-22, 58, 60-65, 67-72, 74-76, 78-84, 86, and 88-91 have been rejected under Section 103 as allegedly obvious over the Simpson patent in view of the Stapleton patent, and, with respect to certain claims, in further view of other secondary references. The Section 103 rejections are traversed for the reasons set forth below.

The Simpson patent discloses a method for the detection of molecules in a sample, wherein the molecules to be detected are amplified via polymerase chain reaction (PCR) prior to electrophoresis and spectroscopic analysis. The Stapleton patent is relied upon for its purported teaching of a method for analyzing nucleic acid samples that requires no amplification.

All of the pending claims, as amended, require analysis (e.g., electrophoresis) of a sample comprising multiple molecules in the form of an *aqueous solution*. Neither the Simpson patent nor the Stapleton patent discloses that samples are analyzed (e.g., via electrophoresis) as an aqueous solution. Instead, the methods disclosed in the Simpson patent and the Stapleton patent require that samples be analyzed within an immobilized medium, such as cross-linked or linear polymer solutions (e.g., polyacrylamide), or other gel matrices.

In this regard, the Stapleton patent discloses, "[t]he sample to be analyzed for the presence of a particular DNA component (or RNA or polypeptide moiety) is suspended in *matrix material* placed in the matrix holding area of the device" (see Stapleton patent at col. 3, lines 25-28, emphasis added). Furthermore, the Stapleton patent discloses that restriction enzymes, ribozymes, or polymerases "may be introduced into the *gel matrix* to act upon the nucleic acids, *which are selectively embedded*" (see Stapleton patent at col. 4, lines 27-35). The matrix material is preferably "a semi-solid material made with agarose or acrylamide or similar polymer, or mixture thereof" (see Stapleton patent at col. 8, lines 43-46). Thus, the Stapleton patent does not disclose subjecting a sample to electrophoresis in an aqueous

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solution, or maintaining a sample in a sample channel as an aqueous solution, as required by the pending claims.

The Office Action alleges that the Simpson patent discloses introducing a sample in free solution to a sample channel. While the Simpson patent discloses that samples can be introduced into the electrophoresis module in the liquid phase, the electrophoresis module comprises a medium through which the samples migrate. For example, the method disclosed in the Simpson patent “consists of simply loading small liquid volumes containing fragment samples...into wells in the *electrophoretic medium* (see Simpson patent at col. 5, lines 52-55, emphasis added). The Simpson patent further discloses an electrophoretic module comprising “rectangular plates spaced slightly apart to define a rectangular sheet of *electrophoretic medium*. Migration occurs in straight, parallel lanes through this medium” (see Simpson patent at col. 6, line 65 - col. 7, line 6, emphasis added). According to the Simpson patent, the separation medium “involves the use of polymer sieving media, either cross-linked gels or linear polymer solutions. Most of these are based on polyacrylamide” (see Simpson patent at col. 19, lines 62-67). In addition, Example 1 of the Simpson patent describes electrophoresis using a 5% monomer 19:1 acrylamide:bisacrylamide gel, which was allowed to polymerize for 3.5 hours before sample loading (see Simpson patent at col. 40, lines 32-39). Thus, the Simpson patent does not disclose subjecting a sample to electrophoresis in an aqueous solution, or maintaining a sample in a sample channel as an aqueous solution, as required by the pending claims.

The Office Action relies upon the Schwartz patent, the Chu patent, the Yguerabide patent, the Hayashizaki patent, and the Brumley patent for their alleged disclosures of photobleaching during nucleic acid sequencing and during electrophoresis, the use of equilateral prisms to enhance the signal to noise ratio in analyte assays, the use of a pinhole in an electrophoresis apparatus, and the use of a microscopic objective lens in an electrophoresis analyzer, respectively. Neither the Schwartz patent, the Chu patent, the Yguerabide patent, the Hayashizaki patent, or the Brumley patent, however, discloses the elements of the pending claims that are absent from the combined disclosures of the Simpson patent and the Stapleton patent. Thus, the cited references do not provide any motivation to combine their disclosures, and, even if combined, the combined disclosures of the cited references do not disclose or suggest the subject matter of the pending claims. Accordingly, the Section 103 rejections should be withdrawn.

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*Conclusion*

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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